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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,320	PROBER ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *2,3,5,12,13 and 48-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-11 and 14-46* is/are rejected.

7)☒ Claim(s) *6,7,11 and 16-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/04;4/04;9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4, 6-11, and 14-47 are drawn to a method for identification of an analyte comprising correlating capture probes with particles, classified in class 356, subclass 300.

II. Claims 2, 4, 6, 7-11, 14-42, and 44-47 are drawn to a method for the identification of an analyte comprising particles affixed in a defined spatial array, classified in class 356, subclass 301.

III. Claims 3, 6, 13, 14, 16-35, 37-43, and 45-47 are drawn to a method for the identification of an analyte comprising identification of a detectable label, classified in class 435, subclass 7.1.

IV . Claims 5, 12, 16-35, 37-42, and 44-47 are drawn to a method of analyte dissociation, classified in class 435, subclass 4.

V. Claims 48-59 are drawn to an identifiable particle, classified in class 435, subclass 518.

VI. Claims 60-70 are drawn to a microparticle based measuring system, classified in class 435, subclass 525.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups I-IV are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The method of group I requires correlating at least one capture probe with each identified particle, which is not required of the methods in groups II or IV; and requires scanning the particles, which is not required by group III. The method of group II requires affixing particles in a defined spatial array, which is not required of the methods in groups I, III, or IV. The method of group III requires analyte comprising a detectable label, which is not required of the methods in groups I, II, or IV. The method of group IV requires dissociating at least one analyte from at least one capture probe of the particle, which is not required of the methods in groups I, II, or III.

3. Inventions of a) each of groups I-IV and b) group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product claimed in group V can be used in any of the processes claimed in groups I, II, III, or IV.

4. Inventions of a) each of groups I-IV and b) group VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed in group VI can be used to practice any of the processes claimed in groups I, II, III, or IV.

5. Inventions of group V and group VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed in claims 48-59, because the system does not require a non-fluorescing particle as recited in claim 48. The subcombination has separate utility such as to aide in separation and filtration of a solution containing analytes.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for one group is not required for the others.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

8. During a telephone conversation with Mr. Neil Feltham on October 19, 2004 a provisional election was made without traverse to prosecute the invention of group I, claims 1, 4, 6-11, and 14-47. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 3, 5, 12, 13, and 48-70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

10. Claims 6, 7, 11, and 16-47 are objected to because of the following informalities: the claims are dependent on non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 7, 19-31, 40, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite because it is unclear how the analytical wavelength range is a window. It is unclear how the analytical wavelength is different from the optical wavelength, and it is vague as to whether the analytical wavelength is within the range of the optical wavelength.

Regarding Claims 19-31, the phrase "substantially transparent" is vague and indefinite because it is unclear how much transparency is substantially, and it is unclear what is meant by transparent to light over the analytical wavelength range.

Claims 28 and 31 are vague and indefinite because it is unclear if nanoparticles and colloidal particles are made from one of the materials listed or if the core/layer can be made from any material if it is a nanoparticle or colloidal particle.

Regarding claim 40, it is unclear if the capture probe is added or bound to the particle surface.

Claim 42 is vague and indefinite because it is unclear how the coating is activated. It is unclear if the coating prevents all binding or if it is specific for the capture probe.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 4, 6, 8, 11, 16-23, 33, 35, and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (US 6,200,820).

Hansen et al. teach a method for the indentification of an analyte comprising: providing a light scanning source which produces light over an analytical wavelength (col. 7, lines 10-13); providing at least two substantially spherical identifiable particles (col. 7, lines 10-13); applying at least one capture probe to the particles which binds to the surface of the particle, the capture probe having affinity for at least one analyte (col. 8, lines 17-28; col. 9, lines 28-34); scanning each particle one or more times over a first analytical wavelength range to produce at least one

first reference resonant light scattering signature for each particle, the first resonant light scattering signature uniquely identifying each particle (col. 9, lines 6-19); correlating the capture probe with each identified particle (col. 9, lines 6-19); contacting the particle with a sample suspected of containing at least one analyte where, if the analyte is present in the sample, binding occurs between the at least one capture probe and the at least one analyte (col. 9, lines 19-22); scanning the particles one or more times over a second analytical wavelength range to produce at least one second binding resonant light scattering signature wherein the first reference and the second resonant light scattering signature are different, and the first and second analytical wavelengths are the same (col. 9, lines 19-30); detecting binding of at least one analyte to at least one capture probe by comparing the differences between the first and second resonant light scattering signatures (col. 8, lines 10-16; col. 10, lines 25-31; col. 11, lines 5-20); and identifying one or more bound analyte on the basis of the correlation and at the second binding resonant light scattering signature (col. 11, lines 5-20).

Hansen et al. also teach the analyte identified by analytical methods (col. 11, lines 5-20), and the amount of bound analyte determined by comparing the differences between the first and second resonant light scattering signatures (col. 8, lines 10-16). Hansen et al. also teach the particle being 1 μm (col. 8, lines 44-48), which falls within the recited ranges of 100 μm or less, 75 μm or less, and 50 μm or less.

Regarding claims 19 and 20, Hansen et al. teach a particle comprising a substantially spherical core and one or more layers overlaying the core; wherein the layers are substantially transparent to light over the analytical wavelength (col. 3, lines 45-60; col. 7, lines 47-49; col. 8,

lines 57-60), wherein the particles are optically (col. 7, lines 41-43; col. 8, lines 53-55), biologically (col. 10, lines 61-66), and chemically (col. 7, lines 28-34) active.

With respect to claims 33 and 35, Hansen et al. teach both the capture probe and the analyte being antibodies (col. 10, lines 58-67).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 7, 9, 10, 14, 15, 24-28, 31, 34, and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US 6,200,820) in view of West et al. (US 6,530,944).

Hansen et al., as disclosed above, teach a method for identification of an analyte, but fail to teach the particle scanned over an analytical wavelength range prior to applying the capture probe.

West et al. teach scanning a particle over an analytical wavelength range in order to observe a shift in the wavelength of maximum resonance (col. 28, line 61 – col. 29, line 4)

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hansen et al., scanning the particle over an analytical wavelength prior to applying the capture probe as taught by West et al., in order to observe a shift in peak wavelength of a specific analyte in a multiple analyte assay.

West et al. also teach a particle scanned over the analytical wavelength range prior to applying the capture probe to produce an identifying resonant light scattering signature (surface plasmon resonance; col. 9, lines 15-30; Fig. 1). West et al. also teach a detectable label of a fluorescent moiety (col. 13, lines 2-20).

Regarding claims 7, 14, and 15, West et al. teach the optical wavelength ranging from about 500 to about 1200 nm (Fig. 1), which partially falls within the recited range of 275 nm to about 1900 nm, and an analytical range of about 30 nm (col. 3, lines 4-8), but fail to teach the exact ranges of an analytical window of about 1 to about 20 nm. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 7, 14, and 15 are for any particular purpose or solve any stated problem, and the prior art teaches that the optical wavelengths and the range of analytical wavelengths may be varied in order to detect

particles that have different optical resonance properties over a wide range of wavelengths, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the optical resonance art.

With respect to claim 24, Hansen et al., as disclosed above, teach a method for identification of an analyte, but fail to teach the particle thickness.

West et al. teach layers being optically (col. 2, lines 25-30), biologically (col. 11, lines 51-57), or chemically (col. 5, lines 8-11) active and having a thickness of 20 nm (Fig. 1; col. 5, lines 38-40), which falls within the recited ranges of 1 nm –10 μm and 1nm – 20μm, in order to control the optical resonance of the particle (col. 9, lines 15-30).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hansen et al., a layer thickness as taught by West et al., in order to separate optical resonance signals when detecting multiple analyte within the same sample.

Regarding claims 25-28, West et al. teach a particle comprising a spherical, light absorbing (col. 8, lines 52-54), core (col. 4, lines 56-63) and a layer over the core (col. 4, lines 22-25). West et al. also teach the core being silica (col. 5, lines 36-40) and the layer being metal colloidal particles (col. 27, lines 62-65). West et al. also teach the analyte being an antibody (col. 19, lines 35-39; col. 20, lines 15-22) present in a sample comprising matrix components (col. 30, lines 54-65). West et al. teach the capture probe synthesized on the surface of the particle (col. 30, lines 34-39) and the capture probe isolated from natural sources (isolated from human breast epithelial carcinoma cell line; col. 30, lines 18-24).

With respect to claim 27, West et al. teach a nanoparticle with a shell layer having a thickness from 1 to 100 nm (col. 10, lines 2-4), which partially falls within the recited range of 50 nm to 20 μm.

Regarding claims 41-44, West et al. teach applying the capture probe to the particle when the particle is treated with a thin film to prevent non-specific binding of sample matrix components (col. 30, lines 46-53). West et al. also teach the first or second binding resonant light scattering signatures being peak wavelength amplitudes and the signatures compared on the basis of spectral features of the peak wavelength amplitudes (Fig. 3a and b; col. 5, lines 44-53).

16. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US 6,200,820) in view of Becker et al. (US 2003/0015428) further in view of Hayashi et al. (US 5,124,207).

Hansen et al., as disclosed above, teach a method for the identification of an analyte, but fail to teach a particle wherein the core is magnetic and iron oxide.

Becker et al. teach a particle wherein the core is a magnetic material, in order to have a conducting core (pgs. 16-17, [0209-0211]) in order to achieve a dielectric fingerprint, but fail to teach the magnetic material being iron oxide.

Hayashi et al. teach a magnetic iron oxide particle comprising a magnetic iron oxide core (col. 1, lines 35-40), in order to achieve particles that are fine in size and high in coercive force.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hansen et al., a magnetic particle as taught by Becker et al., in order to allow for simultaneous manipulation identification, and detection of different species and for multiple analyte in a fluid sample to be indexed. Furthermore, it would

have been obvious to include in the method of Hansen et al. in view of Becker et al., the magnetic material of iron oxide, in order to have particles that are magnetically and chemically stable.

17. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US 6,200,820) in view of Becker et al. (US 2003/0015428).

Hansen et al., as disclosed above, teach a method for the identification of an analyte, but fail to teach a particle wherein the core is hollow.

Becker et al. teach a particle wherein the core is hollow (pg. 4, [0052]) in order to have a conducting core with a dielectric shell so the dielectric properties of the particle can be detected (pg. 19, [0232-0233]).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hansen et al., a particle with a hollow core as taught by Becker et al., in order to allow for simultaneous manipulation, identification, and detection of different species and for multiple analyte in a fluid sample to be indexed.

18. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US 6,200,820) in view of Finlan (US 5,055,265).

Hansen et al., as disclosed above, teach a glass particle used in a method for the identification of an analyte, but fail to teach the index of refraction.

Finlan teaches a block made from high refractive index glass with a refractive index typically of 2 (col. 2, lines 46-51), which falls within the recited range of about 1.45 to about 2.1, in order to achieve total internal reflection of a beam from the source at resonance.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the glass particle of Hansen et al., a refractive index of 2 as taught by Finlan, in order to detect minute changes in the refractive index of the surface as binding occurs.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11/12/04